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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/713,601	11/15/2000	Poonam Agarwal	FORS-04603	9798

23535 7590 08/15/2002

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EXAMINER

HASHEMI, SHAR S

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 08/15/2002

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/713,601	AGARWAL ET AL.	
	Examiner	Art Unit	
	Shar Hashemi	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities:
 - A) The verified statement has not been signed.
 - B) Each figure must correspond to a description. The following figures do not have a corresponding description: 1A-H, 2A-C, 22A-B, 42A-B, 59A-E, 88A-B, 99A-E.
 - C) Each description must correspond to a figure. The following descriptions do not have a corresponding figure: 3A-G, 4A-B, 107.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 & 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- A) The active steps in claim 1 render claims 1-6 confusing because the preamble recites a method for detecting a target sequence while the active steps do not recite detecting a target sequence.

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B) Claims 5 & 10 recite the following limitations: "said first portion" (page 332, line 30; page 333, line 23) "said second portion" (page 333, line 2). There is insufficient antecedent basis for this limitation in the claim. The phrase "said [first or second] portion of said target nucleic acid" is confusing because the claim language utilizes "first region" and "second region" when referring to target nucleic acid.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Hall et al (US 5, 994, 069 November 20, 1999).

Hall et al in US 5, 994, 069 teach a method and kit for detecting a target sequence comprise utilizing a sample containing target sequence (col. 1, lines 25-39; col. 7, lines 16-67),

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utilizing oligonucleotides having the ability to form an invasive cleavage structure in the presence of target sequence (col. 7, lines 21-24), utilizing an agent to detect the presence of an invasive cleavage structure (col. 10, lines 15-34), exposing the sample to the oligonucleotides and agent (col. 8, lines 25-39). They further teach that in the exposing step the invasive cleavage structure is formed between the target sequence and oligonucleotides when the target sequence is present in the sample and the invasive cleavage structure is cleaved by the cleavage agent to form a cleavage product (col. 8, lines 8, lines 25-39). They teach a step of detecting the cleavage product (col. 8, lines 38-67). They teach the target sequence comprise a first and second region where the second region is downstream and contiguous to the first region (col. 7, lines 23-29). They also teach oligonucleotides comprise first and second oligonucleotides where a portion of the first oligonucleotide is complementary to the first portion of the target sequence and where the second oligonucleotide has a 3' and 5' portion where the 5' portion is complementary to the second region of the target sequence (col.12, line 1-51). They teach the target sequence is human cytomegalovirus viral DNA (col. 13, lines 42-67; col. 168, lines 50-67).

SUMMARY

4. No claims allowed.

CONCLUSION

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shar Hashemi whose telephone number is (703) 305-4840 and whose e-mail address is shar.hashemi@uspto.gov. However, the Office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner is on flex-time schedule and can be best reached on weekdays from 7:00 a.m. to 3:30 p.m. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119.

Any inquiry of a general nature, matching or filed papers or relating to the status of this application or proceeding should be directed to the Sharon Thornton for Art Unit 1637 whose telephone number is (703)-305-3001.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Center numbers for Group 1600 are Voice (703) 308-1235 and Before Final FAX (703) 872-9306 or After Final FAX (703) 308-9307.

August 11, 2002



JEFFREY SIEW
PRIMARY EXAMINER

8/12/02